Message Text

PAGE 01 STATE 126575

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INFO OCT-01 AF-06 ARA-10 EUR-12 EA-10 NEA-10 ISO-00 OES-05

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DHEW/OIH/MACODDING
EA/RA:RMARTENS (INFO)
NEA/RA:TGRANT (INFO)
OES/EX:AEPARDEE
AF/RA:JAANDEREGG (INFO)
EUR/NSC-IG:JROUSE (INFO)
ARA/NSC-IG:RJBLOOMFIELD (INFO)
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FM SECSTATE WASHDC
TO AMEMBASSY BUENOS AIRES
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PAGE 02 STATE 126575

AMEMBASSY RABAT
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AMCONSUL HAMILTON
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AMEMBASSY SANTO DOMINGO
AMEMBASSY QUITO
AMEMBASSY SAN SALVADOR
AMEMBASSY GUATEMALA
AMEMBASSY PORT AU PRINCE
AMEMBASSY TEGUCIGALPA
AMCONSUL HONG KONG
AMEMBASSY KINGSTON
AMEMBASSY TOKYO
AMEMBASSY SEOUL
AMCONSUL MARTINIQUE
AMCONSUL CURACAO
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AMEMBASSY CARACAS
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PAGE 03 STATE 126575

UNCLAS STATE 126575

E.O. 11652: N/A
TAGS: OGEN, ETRD, TBIO, XX

SUBJ: FDA ADVISORY - DEFECTIVE ELCTRONIC PRODUCT - EXCESSIVE ULTRA-VIOLET RADIATION

1. FDA ADVISES THAT THE NUVA-LITE ULTRAVIOLET DENTAL APPLIANCE MANUFACTURED BY THE L.D. CAULK COMPANY, DIVISION OF DENTSPLY INTERNATIONAL INC., LAKEVIEW AVE., MILFORD, DELAWARE 19963 IS DEFECTIVE UNDER THE REGULATIONS OF THE RADIATION CONTROL FOR HEALTH AND SAFETY ACT OF 1968. THIS DEVICE IS USED BY DENTISTS

FOR POLYMERIZING DENTAL FILLER AND SEALANT MATERIAL. THE UNITED STATES FOOD AND DRUG ADMINISTRATION'S BUREAU OF RADIOLOGICAL HEALTH IS NOW REQUIRING ALL DENTISTS TO IMMEDIATELY DISCONTINUE USE OF THE NUVA-LITE UNTIL THIS DEVICE HAS BEEN MODIFIED TO ELIMINATE ALL POS-SIBILITY OF UNNECESSARY ULTRAVIOLET EMISSIONS WHICH PRESENT A RISK OF INJURY. THESE INCLUDE EYE IRRITATIONS AND MINOR SKIN BURNS.

2. THE FOLLOWING BACKGROUND INFORMATION IS RELEVANT TO THIS ADVISORY:

A. IT WAS DETERMINED THAT IN NOVEMBER 1971 THE FIRM HAD BEEN AWARE OF A RADIATION LEAKAGE DEFECT FROM THE LOUVERS ON THE LEFT SIDE OF THE HOUSING AND SENT RETROFIT BAFFLES TO DEALERS AND DISTRIBUTORS WITHOUT REPORTING SUCH DEFECT TO THE BUREAU PURSUANT TO REGULATIONS.

B. ON FEBRUARY 19, 1975 A CORRECTIVE ACTION PLAN WAS APPROVED BY THE BUREAU TO REMEDY A DEFECT WHICH PERMITTED UNNECESSARY ULTRA-VIOLET RADIATION (1) ALONG THE AXIS AND THROUGH THE BEND OF THE QUARTZ APPLICATOR PIPE AND (2) THROUGH THE LOUVERS IN THE HOUSING OF THE MERCURY VAPOR LAMP. THE RADIATION FROM THE BEND IN THE PIPE IS EMITTED IN A FORWARD DIRECTION EXPOSING THE SOFT TISSUES IN THE PATIENT'S MOUTH TO FILTERED ULTRAVIOLET LIGHT (340-400NM). THE RADIATION FROM THE HOUSING IS EMITTED IN A BACKWARD DIRECTION EXPOSING THE USER (DENTIST) TO UNFILTERED ULTRAVIOLET LIGHT (200-400 NM). ULTRAVIOLET RADIATION HAVING WAVELENGHS WITHIN A RANGE OF 254-300 NM HAVE BEEN SHOWN TO PRODUCE SKIN CANCER, AND ALTERATIONS OF THE EYE LENS AND THE AQUEOUS HUMOR PROTEIN OF THE EYE. THE CORRECTIVE ACTION CONSISTED OF THE FOLLOWING:
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PAGE 04 STATE 126575

(1) IN ADDITION TO NOTIFICATION TO PURCHASERS, AS IDENTIFIED THROUGH COMPNAY RECORDS, A GENERAL MAILING WAS SENT TO ALL DENTISTS EXPLAINING THE PROBLEM AND REQUESTING THAT THOSE WHO HAVE NUVA-LITE UNITS ADVISE THE COMPANY OF THIS FACT.

(2) EACH DENTIST IDENTIFIED AS A PURCHASER OF A NUVA-LITE UNIT WILL BE MAILED THREE BLACK TEFLON SLEEVES AND THREE METAL SHIELDS. THE SHIELDS ARE TO BE PLACED IN THE HOUSING, AND A SINGLE SLEEVE IS INTENDED TO BE PLACED OVER THE BEND IN THE QUARTZ ROD WHEN IN USE. THE ADDITIONAL SLEEVES ARE PROVIDED IN THE EVENT THAT A SLEEVE IS LOST OR DAMAGED. A CAUTION LABEL WILL BE INCLUDED IN THE
KIT TO BE AFFIXED TO THE CONSOLE AS A REMINDER THAT A TEFLON SLEEVE IS TO BE IN PLACE WHENEVER THE NUVA-LITE IS USED.

C. ON THE BASIS OF LABORATORY TESTING AND EXAMINATION OF THE FIRM'S TEST RESULTS, THE BUREAU OF RADIOLOGICAL HEALTH HAS DETERMINED THAT THE NUVA-LITE DENTAL APPLIANCE HAS AN ADDITIONAL DEFECT. THE PRODUCT EMITS UNFILTERED ULTRAVIOLET RADIATION FROM THE HOUSING SEAM IN A FORWARD DIRECTION, APPROXIMATELY 30 DGRS ABOVE AND BELOW THE HORIZONTAL AXIS OF THE DEVICE. THIS DEFECT APPEARS TO BE THE RESULT OF MISMATCHING OF COMPONENTS DURING FABRICATION AND

IS NOT CORRECTABLE BY THE PROGRAM PRESENTLY BEING CONDUCTED.

D. AS A RESULT, FDA HAS REQUESTED THE MANUFACTURER TO DISCONTINUE ALL SALES, RENOTIFY ALL AFFECTED PERSONS OF THE THIRD DEFECT, INSTRUCTING THEM TO IMMEDIATELY DISCONTINUE USE OF THE NUVA-LITE UNTIL THE DEVICE HAS BEEN FURTHER MODIFIED TO ELIMINATE ALL POSSIBILITY OF UNNECESSARY ULTRAVIOLET EMISSIONS WHICH PRESENT A RISK OF INJURY.

3. POSTS ARE REQUESTED TO INFORM HOST GOVERNMENTS HEALTH AUTHORITIES OR APPROPRIATE AGENCY EXERCISING JURISDICTION OVER SUCH DEVICES, OF THE VARIOUS DEFECTS ASSOCIATED WITH THE NUVA-LITE ULTRAVIOLET DENTAL APPLIANCE, TO TAKE SUCH ACTION AS THEY DEEM APPROPRIATE.

4. FOREIGN DISTRIBUTION AS FOLLOWS:

SUBSIDIARIES

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PAGE 05 STATE 126575

ARGENTINA 352; BRAZIL 3,728; MEXICO 392

AMALCO TERRITORIES

ALGERIA 6; AUSTRALIA 859; BELGIUM 326; BYPRUS 21; DENMARK 375; ENGLAND 2,373; FINLAND 62; FRANCE 101; GERMANY 2,727; GREECE 35; ICELAND 10; INDONESIA 31; IRAN 49; ITALY 1,723; JORDAN 1; KENYA 3; KUWAIT 4; LEBANON 65; MOROCCO 3; NETHERLANDS 16; NEW ZEALAND 9; NORWAY 3; PORTUGAL 123; SINGAPORE 26; SO. AFRICA 410; SPAIN 334; SWEDEN 118; SWITZERLAND 345; THAILAND 24; TUNISIA 3; TURKEY 71; U.S.S.R. 1; YOGOSLAVIA 100.

EXPORT TERRITORIES

BARBADOS 1; BERMUDA 11; BOLIVIA 18; CHILE 20; COLOMBIA 38; COSTA RICA 66; DOMINICAN REPUBLIC 85; ECUADOR 25; EL SALVADOR 22; GUADELOUP
E
3; GUATEMALA 74; HAITI 6; HOND
URAS 10; HONG KONG 211; JAMAICA 32;
JAPAN 2,310; KOREA 30; MARTINIQUE 1; NETHERLANDS ANTILLES 22;
NICARAGUA 21; PANAMA 22; PERU 246; PHILIPPINES 93; TAIWAN 20; VEN-
EZUELA 96; AND TRINIDAD 24.
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MEXICO
ALGIERS
CANBERRA
BRUSSELS

NICOSIA
COPENHAGEN
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